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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/806,125	03/28/2001	Etsuya Matsutani	2556USOP	7053

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TAKEDA PHARMACEUTICALS NORTH AMERICA, INC
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EXAMINER

RAWLINGS, STEPHEN L

ART UNIT PAPER NUMBER

1642

DATE MAILED: 02/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/806,125	Applicant(s) MATSUTANI ET AL.	
	Examiner Stephen L. Rawlings, Ph.D.	Art Unit 1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-11 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The election with traverse filed October 31, 2003 is acknowledged and has been entered.
2. Upon consideration of Applicant's grounds of traversal of the restriction and election requirement, the previous Office action mailed October 3, 2003 is vacated and replaced by this Office action.
3. Claims 1-11 are pending in the application and are currently subject to the following restriction.

Election/Restrictions

4. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

A. Claims 1-4 and 6-11 are generic to a plurality of species of invention wherein said hormonal agent is selected from the group consisting of the following:

1. The peptide of SEQ ID NO: 1, wherein Y is D-Leu and Z is NH-C₂H₅ or a salt thereof;
2. The peptide of SEQ ID NO: 1, wherein Y is D-Leu and Z is Gly-NH₂ or a salt thereof;
3. The peptide of SEQ ID NO: 1, wherein Y is D-Ala and Z is NH-C₂H₅ or a salt thereof;
4. The peptide of SEQ ID NO: 1, wherein Y is D-Ala and Z is Gly-NH₂ or a salt thereof;
5. The peptide of SEQ ID NO: 1, wherein Y is D-Trp and Z is NH-C₂H₅ or a salt thereof;

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6. The peptide of SEQ ID NO: 1, wherein Y is D-Trp and Z is Gly-NH₂ or a salt thereof;
7. The peptide of SEQ ID NO: 1, wherein Y is D-Ser (tBu) and Z is NH-C₂H₅ or a salt thereof;
8. The peptide of SEQ ID NO: 1, wherein Y is D-Ser (tBu) and Z is Gly-NH₂ or a salt thereof;
9. The peptide of SEQ ID NO: 1, wherein Y is D-2Na1 and Z is NH-C₂H₅ or a salt thereof;
10. The peptide of SEQ ID NO: 1, wherein Y is D-2Na1 and Z is Gly-NH₂ or a salt thereof;
11. The peptide of SEQ ID NO: 1, wherein Y is D-His (ImBzl) and Z is NH-C₂H₅ or a salt thereof; and
12. The peptide of SEQ ID NO: 1, wherein Y is D-His (ImBzl) and Z is Gly-NH₂ or a salt thereof.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

The special technical feature of species 1 is producing and using a peptide of SEQ ID NO: 1, wherein Y is D-Leu and Z is NH-C₂H₅ or a salt thereof;

The special technical feature of species 2 is producing and using a peptide of SEQ ID NO: 1, wherein Y is D-Leu and Z is Gly-NH₂ or a salt thereof;

The special technical feature of species 3 is producing and using a peptide of SEQ ID NO: 1, wherein Y is D-Ala and Z is NH-C₂H₅ or a salt thereof;

The special technical feature of species 4 is producing and using a peptide of SEQ ID NO: 1, wherein Y is D-Ala and Z is Gly-NH₂ or a salt thereof;

The special technical feature of species 5 is producing and using a peptide of SEQ ID NO: 1, wherein Y is D-Trp and Z is NH-C₂H₅ or a salt thereof;

The special technical feature of species 6 is producing and using a peptide of SEQ ID NO: 1, wherein Y is D-Trp and Z is Gly-NH₂ or a salt thereof;

The special technical feature of species 7 is producing and using a peptide of SEQ ID NO: 1, wherein Y is D-Ser (tBu) and Z is NH-C₂H₅ or a salt thereof;

The special technical feature of species 8 is producing and using a peptide of SEQ ID NO: 1, wherein Y is D-Ser (tBu) and Z is Gly-NH₂ or a salt thereof;

The special technical feature of species 9 is producing and using a peptide of SEQ ID NO: 1, wherein Y is D-2Na1 and Z is NH-C₂H₅ or a salt thereof;

The special technical feature of species 10 is producing and using a peptide of SEQ ID NO: 1, wherein Y is D-2Na1 and Z is Gly-NH₂ or a salt thereof;

The special technical feature of species 11 is producing and using a peptide of SEQ ID NO: 1, wherein Y is D-His (ImBzl) and Z is NH-C₂H₅ or a salt thereof; and

The special technical feature of species 12 is producing and using a peptide of SEQ ID NO: 1, wherein Y is D-His (ImBzl) and Z is Gly-NH₂ or a salt thereof.

Accordingly, species 1-12 do not share the same or corresponding special technical feature so as to form a single general inventive concept under PCT Rules 13.1 and 13.2.

B. Claims 1-4 and 6-11 are further generic to a plurality of species of invention wherein said composition comprises an agent that inhibits the action of a cell growth factor or receptor thereof, wherein said cell growth factor is selected from the group consisting of the following:

- A. EGF or a substance possessing substantially the same activity as EGF;
- B. insulin or a substance possessing substantially the same activity as insulin; and
- C. FGF or a substance possessing substantially the same activity as FGF.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

The special technical feature of species A is providing an agent that inhibits the action of a cell growth factor or receptor thereof, wherein said cell growth factor is EGF or a substance possessing substantially the same activity as EGF.

The special technical feature of species B is providing an agent that inhibits the action of a cell growth factor or receptor thereof, wherein said cell growth factor is insulin or a substance possessing substantially the same activity as insulin.

The special technical feature of species C is providing an agent that inhibits the action of a cell growth factor or receptor thereof, wherein said cell growth factor is FGF or a substance possessing substantially the same activity as FGF.

Accordingly, species A-C do not share the same or corresponding special technical feature so as to form a single general inventive concept under PCT Rules 13.1 and 13.2.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

5. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion


7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen L. Rawlings, Ph.D. whose telephone number is (571) 272-0836. The examiner can normally be reached on Monday-Friday, 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne (Bonnie) Eyler, Ph.D. can be reached on (571) 272-0871. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Stephen L. Rawlings, Ph.D.
Examiner
Art Unit 1642

slr
February 4, 2004


YVONNE EYLER, PH.D.
SUPERVISORY PATENT EXAMINER
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